DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Joe Barton
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

DEC 2 8 2006

Dear Mr. Chairman:

Thank you for your letter of October 24, 2006, co-signed by Representative Ed Whitfield, in which you expressed interest in whether the Food and Drug Administration's (FDA) food security projects were leveraged to prevent and/or detect outbreaks such as *E. coli* in spinach. You asked specific questions about Operation Liberty Shield (OLS) and about the FDA Security Surveillance Assignment (FSSA). As you know, FDA provided a briefing for your staff on December 8, 2006, during which we responded to your questions. We are now providing a written response, as requested.

We repeat your questions and respond below:

1. List of the five different food commodities selected for assignment and the rationale for each product's selection for OLS and the FDA product codes of product covered (necessary for targeting in OASIS (Operational and Administrative System for Import Support)). Please also provide the date(s) of the vulnerability assessment(s) undertaken by FDA that determined the selection of the commodities. Please also identify the original list of food products from which the five different food commodities were selected and explain how the original list of food products was determined.

The eight products identified for food security coverage under OLS were:

- Botanical and herbal dietary supplements;
- Cosmetic creams for body, face and hand, cleansing, moisturizing and night creams;
- Fluid milk;
- Fresh leaf and stem vegetables, including cut leaf and stem vegetables;
- Fruit and vegetable juice (refrigerated or shelf stable), including concentrate;
- Powdered infant formula;
- Spices; and
- Spring and mineral water, bottled.

The information on FDA product codes is contained in the OLS assignments documents we have already provided your staff. The vulnerability assessment was conducted in March 2002.

The original list of food products was developed based on input from FDA personnel and industry trade associations. It represents products that presented a heightened potential for tampering, criminal, malicious, or terrorist activity. The list of original food products is provided below:

- Baby Food
- Breaded Food
- Canned food, low-acid
- Cereal
- Deli Salads
- Dietary Supplements
- Entrees, cooked
- Flour
- Fruit Juice
- Gum arabic (ingredient)
- High fructose corn syrup (ingredient)
- Honey
- Ice Cream
- Infant Formula
- Milk
- Peanut Butter
- Produce
- Seafood, cooked
- Soft Drinks
- Spices
- Vitamins
- Yogurt
- Water, bottled

2. List of the five different food commodities selected for assignment and the rationale for each product's selection for FSSA and the FDA product codes of products covered (necessary for targeting in OASIS (Operational and Administrative System for Import Support)). Please also provide the date(s) of the vulnerability assessment(s) undertaken by FDA that determined the selection of the commodities. Please also identify the original list of food products from which the five different food commodities were selected and explain how the original list of food products was determined.

The five assigned products for food security under the FSSA were:

- Fluid milk;
- Fresh (not frozen) leaf and stem vegetables, including cut leaf and stem vegetables;
- Fruit and vegetable juice (refrigerated or shelf stable), including concentrate;
- Infant formula; and
- Spring and mineral water, bottled.

FDA product codes are noted in the document entitled, "FDA Security Surveillance Assignments," which we have already provided to your staff. The vulnerability assessment was conducted in March 2002.

The original list of food products was developed based on input from FDA personnel and industry trade associations. It represents products that presented a heightened potential for tampering, criminal, malicious, or terrorist activity. The list of original food products is the same as the list provided in response to your first question above.

3. For the FSSA:

a. Total number of lines of entry selected for coverage by FDA product code processed by OASIS;

The total number of items was 14,805. We have previously provided a chart that shows the number of lines reviewed for each of the five different food commodities by specific FDA product code.

b. Total number and identification of countries of origin of products covered;

The commodities reviewed under the FSSA originated from 97 countries. We have already provided a chart that reflects the countries of origin and the numbers of line items reviewed from each.

c. Total number of foreign shippers of entries selected for physical examination in the field;

During the FSSA, FDA determined that there were 134 foreign shippers represented.

d. Total number of foreign manufacturers related to lines of entry selected for physical examination;

During the FSSA assignment, there were 122 foreign manufacturers represented.

e. Total number of importers related to lines of entry selected for physical examination;

During the FSSA, out of the total number of imported lines selected for physical examination in the field, FDA determined that there were 122 unique foreign importers represented.

f. Amount of time reported for each unique physical examination;

The reporting time totaled 1,390.3 hours for import physical examinations. FDA's data systems do not have a way of breaking down the data for each unique physical exam.

g. Number of lines of entry that were physically examined (eyes on) by field consumer safety officers and inspectors (CSO/CSIs). Please categorize by FDA product code;

CSOs/CSIs conducted 266 field exams.

h. Number of lines of entry physically sampled by CSO/CSIs and analyzed by FDA laboratories;

FDA laboratories analyzed 238 samples during FSSA, and participating Food Emergency Response Network (FERN) laboratories analyzed 276 samples. (NOTE: Some samples were split between FDA and non-FDA FERN laboratories to allow for both chemical and microbiological analyses.)

i. Number of physical samples collected and analyzed, and provide final classification of sample results (NAI, VAI, OAI). Categorize by FDA product code.

During the FSSA, FDA tracked sample analysis information based on five designations (water, juice, vegetable/produce, infant formula, and milk). Although we do have documentation of each sample, including product code, it would take considerable time to re-format the existing sample summary report to include this information.

276 Samples were collected				
Period 1		Period 2		Milk
Water	47	Vegetable	41	124
Juice	50	Infant Formula	14	

The samples that were collected and analyzed were not classified as to final sample results; however, all samples analyzed were found negative for all bioterrorism agents for which they were analyzed.

There were 276 samples collected. (NOTE: Some samples were split between FDA and non-FDA FERN laboratories to allow for both chemical and microbiological analyses.) This explains the different numbers in the samples collected.

4. For the FSSA, a copy of all reports covering each physical examination of product with results reported by the CSO/CSIs. Reports should include number of units physically examined.

Due to the sensitive nature of these assignments, traditional reports were not prepared. Therefore, we are unable to meet this request.

5. Copies of directions issued to the field implementing OLS and FSSA assignments.

FDA has already provided copies of these assignments to your staff.

6. One of the activities of the FSSA was to "identify gaps in the system for responding to a period of increased food defense risk so that they may be addressed to enhance

preparedness." In its summary report, FDA stated that gaps were identified in the food distribution system, many of the gaps identified in the assignment were resolved, and that FDA "is better prepared to respond to an intentional food contamination event." Please identify the gaps found in the FSSA, what measures FDA implemented to resolve these gaps, and/or any other measures proposed by FDA to resolve these gaps but have not been implemented.

FDA provided a general, unclassified discussion on this issue with committee staff on December 8, 2006.

7. Was spinach included in any of the high-risk food commodities selected for assignment in either OLS or FSSA? If so, what gaps were found in connection with spinach or its food commodity category? What action did FDA take?

Green leafy vegetables were one of the targeted high-risk food commodities. However, we are unable to determine whether any spinach was identified for specific assignment under OLS. For FSSA, spinach was included as a high risk food commodity, and the FDA Prior Notice Center reviewed shipment information on 494 lines of imported spinach during this assignment. The FDA Prior Notice Center review did not identify any of the spinach shipments for the highest priority field examination or sampling assignment.

The two primary goals of the FSSA were:

1. To deter intentional contamination of food through heightened and targeted preventive activities at various points in the chain of supply; and,
2. To exercise the planning and implementation of the system for responding to a period of increased food security risk to identify and address gaps in the system.

Since these goals were not commodity specific, the gaps identified during the FSSA relate only to the implemented systems and were not connected directly to spinach or any specific food commodity category.

8. Was any FSSA process used for analyzing spinach during FDA's ongoing spinach outbreak investigation?

Yes, several FERN processes that were used for the FSSA were utilized for the spinach outbreak. For example, FSSA samples were tested for *E. coli* O157:H7 using a FERN interim counterterrorism method. After the assignment, the FERN National Program Office sent out detailed questionnaires seeking feedback on all the methods utilized for FSSA. This feedback was used to make improvements in all the methods involved with FSSA, including the *E. coli* method. This method was new for the FSSA and incorporated the rapid testing ability of real-time polymerase chain reaction. FERN was able to increase the sensitivity of the assay, improving the levels of detection for the pathogen. This served us well when the improved method was used by FERN and the CDC's Laboratory Response Network for detecting *E. coli* O157:H7 in spinach. The increased level of detection was necessary for some of the spinach samples with low levels of contamination. FSSA served to improve the rapid detection method being used for *E. coli* O157:H7.

In addition to providing the methodology used for the spinach outbreak, FERN provided the necessary specialized reagents needed to run the assay. This was done through the FERN storeroom. This supplying of reagents for the spinach outbreak was greatly facilitated by the experience gathered during FSSA. Reagents for several of the methods used for FSSA were supplied from the storeroom, and valuable experience was gained in shipping and packaging and in ordering protocols. The provision of reagents was also improved by the feedback gathered by FERN from the laboratories that participated in FSSA. This feedback allowed for the providing of reagents to the labs analyzing spinach samples in a seamless manner.

9. According to FDA's Summary Report, the Prior Notice Center identified 38 import entries as Priority One. What were the results of the examinations of these entries?

Priority One assignments conducted by the FDA field investigators included reconciliation examinations and sample collections. The reconciliation examinations were conducted to determine any loss of product security and integrity, to look for intentional product tampering or other signs of loss of integrity, to verify the contents were what they purport to be, and to look for other anomalies between individual units and cases in the subject lots to suggest that the lots had been intentionally altered. Samples collected on these items were analyzed for specific pathogenic microorganisms and harmful chemical agents.

There were no adverse results requiring regulatory action from any of the field examinations or sample collections for the 38 import lines classified and assigned as Priority One by the FDA Prior Notice Center. One sample of Passion Fruit Concentrate was reported to contain cyanide at a level of 4.16 μg/ml. However, this level was well within the range of what is reported to occur naturally in this product and is not considered to be a health hazard. As such, no regulatory action was indicated, and no intentional contamination was suspected.

10. According to FDA's Summary Report, eight FDA laboratories were part of the Food Emergency Response Network (FERN). Please identify the eight FDA laboratories by location and the nature of the lab work conducted. Is the FDA proposing to close down any of the laboratories? If so, which ones and why?

The laboratories are:
Arkansas Regional Laboratory, Jefferson, AR, chemistry and microbiology;
Denver District Laboratory, Denver, CO, chemistry and microbiology;
Kansas District Laboratory, Lenexa, KS, chemistry;
Northeast Regional Laboratory, Jamaica, NY, chemistry and microbiology;
Pacific Regional Laboratory Northwest, Bothell, WA: chemistry and microbiology;
Pacific Regional Laboratory Southwest, Irvine, CA: chemistry and microbiology;
San Francisco District Laboratory, San Francisco, CA: chemistry and microbiology; and
Southeast Regional Laboratory, Atlanta, GA: chemistry and microbiology;

FDA's Office of Regulatory Affairs (ORA) is currently conducting a strategic planning process. At this time, the plan has not been finalized; therefore there are no changes to ORA's current laboratory structure.

11. During the FSSA, how long did it take from the time of collection for samples to be processed for analysis in FERN laboratories and the results communicated to any FERN lab that wanted to see the results of that risk product?

During the assignment, the average time from sample collection date to sample completion date was 15.8 days. Analytical results were entered into the FDA Field Accomplishments and Compliance Tracking System (FACTS) and the electronic laboratory exchange network (eLEXNET). Data were entered into each system using secure procedures that prevented results from being released to the public. Throughout the duration of the assignment, FDA personnel ran bi-weekly reports in each reporting system to capture sample results. On December 21, 2004, notification that all sample analysis was completed and all samples were negative was submitted to appropriate FDA management. On January 27, 2005, there was an FSSA 50-State conference call which discussed the assignment. FERN laboratories that participated in the assignment were able to participate in the 50-State call as well.

12. According to FDA's Summary Report, 276 samples were collected during the FSSA and analyzed by the FERN laboratories. All sample results were negative. One of the major goals of the FSSA was to test preparedness. In light of this goal, would a better assessment of preparedness have been to test the lab networks by including a few samples with positive results and see how this information was actually processed through the system?

FDA utilizes multiple mechanisms to assess the preparedness of our laboratory network. This assignment was not an exercise that warranted the use of "spiked" samples. We routinely conduct proficiency tests to ensure the capability of FERN laboratories and run exercises to make certain that the systems analysis functions properly.

Thank you again for your letter. If you have additional questions or concerns, please let us know. A similar response is being sent to Representative Whitfield.

Sincerely,

David W. Boyer
Assistant Commissioner
for Legislation